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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/672,891
Filing Date: September 26, 2003
Appellant(s): STINSON, JONATHAN S.

Dorothy P. Whelan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 19 May 2008 appealing from the Office action mailed 1 April 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: The previous rejection of claims 1-6, 9-12, 14-15 and 18-21 under 35 U.S.C. 112, first paragraph, as failing to comply with

the written description requirement is withdrawn. The rejection of claims 1-6, 9-10, 12, 14-15 and 19 under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129) is to be reviewed on Appeal. The rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129), and further in view of Scott et al. (US 5,383,928) is to reviewed on Appeal. The rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129), with evidence from Wiktor (US 5,653,727) is to be reviewed on Appeal. The rejection of claims 1-6, 11, 12, 14, 15, 19 and 41 under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503) is to be reviewed on Appeal. The rejection of claims 16-18 under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503), and further in view of the ASM Handbook Volume 2 is to be reviewed on Appeal. The rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503), and further in view of Scott (US 5,383,928) is to be reviewed on Appeal. The rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503), with evidence form Wiktor (US 5,653,727) is to reviewed on Appeal.

NEW GROUND(S) OF REJECTION

Upon further consideration, claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 5,643,312	Fischell et al.	07-1997
US 4,040,129	Steinemann et al.	08-1977
US 5,728,158	Lau et al.	03-1998
US 3,161,503	Lenning et al.	12-1964
US 5,383,928	Scott et al.	12-1995
US 5,653,727	Wiktor	08-1997

Davis, Joseph R., "Properties and Selection: Nonferrous Alloys and Special-Purpose Materials" ASM Handbook, Volume 2, October 1991, pp. 588.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-6, 9-10, 12, 14, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al .(US

4,040,129).

In regards to claims 1, 6, 9-10, 12, 14 and 15, Fischell et al. ('312) discloses a balloon expandable stent that would comprise a tubular body wherein the stent would be fabricated from titanium or titanium alloy (Figure 6, col. 1, line 66 - col. 2, line 3 and col. 4, lines 5-19).

Fischell et al. ('312) discloses a balloon expandable stent having a tubular body that would be made from titanium or titanium alloy as shown above. However, Fischell et al. ('312) does not specify the compositions of biocompatible titanium alloys suitable for use as the stent.

Steinemann et al. ('129) discloses a corrosion resistant alloy that would be used as screws fixed in bones (col. 2, lines 27-46 and col. 4, line 51 - col. 5, line 9) comprising from 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium (col. 3, lines 47-58). These alloys combine corrosion resistance, compatibility, and high strength for uses in surgery (col. 4, lines 25-29).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a balloon expandable stent comprising a tubular body, as disclosed by Fischell et al. ('312), from alloys having 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium, as disclosed by Steinemann et al. ('129), in order to combine corrosion resistance, compatibility, and high strength for uses in surgery (balloon expandable

stent), as disclosed by Steinemann et al. ('129) (col. 4, lines 25-29).

In regards to the limitations that the alloy have a yield strength of 45 ksi or more, a magnetic susceptibility of about +1 or less, and a mass absorption coefficient of about 1.9 cm^2/g or more of claim 1, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a UTS of about 90 ksi or more and a percent elongation of about 40 or more of claim 2, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a yield strength of about 50 ksi or greater, a percent strength to peak load of about 30 or greater, a UTS of about 90 or greater and a percent strength to fracture of about 40 or greater of claim 3, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitation that the alloy has a magnetic susceptibility of about 3.5×10^{-3} or less of claim 4, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 . I. In regards to the limitation that the alloy have a mass absorption coefficient of about 2.9 cm^2/g or less of claim 5, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to claim 19, Fischell et al. ('312) discloses that the stent would be 0.1 to 0.3 mm (0.0039 to 0.012 inches) thick (col. 4, lines 20-26).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129), and further in view of Scott et al. (US 5,383,928).

In regards to claim 20, Fischell et al. ('312) in view of Steinemann et al. ('129) disclose a balloon expandable stent that would comprise a tubular body wherein the stent would be fabricated from titanium or titanium alloy and the titanium alloy would contain 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium.

Fischell et al. (‘312) in view of Steinemann et al. (‘129) discloses balloon expandable, tubular-bodied stents and the compositions thereof as shown above. However, Fischell et al. ('312) in view of Steinemann et al. ('129) does not specify that the body would include a therapeutic agent.

Scott et al. ('928) discloses applying a sheath comprising a polymer and a drug for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen in order to allow controlled release of the drug (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a sheath comprising a polymer and a drug, as disclosed by Scott et al. ('928), to the balloon expandable stent, as disclosed by Fischell et al. ('312) in view of Steinemann et al. ('129), in order to allow controlled release of the

drug, as disclosed by Scott et al. ('928) (abstract).

Claims 1-6, 11-12, 14-15, 19 and 41 are rejected under 35 U.S.C. 103(a)as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503).

In regards to claims 1, 11-12 and 14-15, Lau et al. ('158) discloses a balloon expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium or tantalum alloy where corrosion resistance would be desired (Figures 2-4, col. 7, lines 5-8 and col. 8, line 30).

Lau et al. ('158) discloses a balloon expandable comprising a tubular body that would be made from titanium or tantalum alloys as shown above. However, Lau et al. ('158) does not specify the composition of the alloys that would be suitable for use as the stent.

Lenning et al. ('503) discloses an alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium (col. 2, lines 20-26). This alloy would have improved corrosion resistance and a lower cost relative to pure tantalum (col. 2, lines 7-19).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a balloon expandable stent comprising a generally tubular body, as disclosed by Lau et al. ('158), from alloys having 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the

balance being titanium, as disclosed by Lenning et al ('503), in order to improve corrosion resistance and lower cost, as disclosed by Lenning et al. ('503).

In regards to the limitations that the alloy have a yield strength of 45 ksi or more, a magnetic-susceptibility of about +1 or less, and a mass absorption coefficient of about 2.9 cm^2 /g or more of claims 1 and 41, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a UTS of about 90 ksi or more and a percent elongation of about 40 or more of claim 2, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a yield strength of about 50 ksi or greater, a percent strength to peak load of about 30 or greater, a UTS of about 90 or greater and percent strength to fracture of about 40 or greater of claim 3, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitation that the alloy has a magnetic susceptibility of about 3.5×10^{-3} or less of claim 4, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitation that the alloy have a mass absorption coefficient of

about 2.9 cm^2 /g or less of claim 5, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to claim 19, Lau et al. ('158) discloses that the thickness of the tubing would be about 0.003 inches, which would be within the ranges of 0.0015 inch and about 0.0150 inch (col. 7, lines 5-15).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503), and further in view of the ASM Handbook Volume 2.

In regards to claims 16, Lau et al. ('158) in view of Lenning et al. ('503) discloses a balloon expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium and/or tantalum alloy and corrosion resistance would be desired as shown above, but Lau et al. ('158) in view of Lenning et al. ('503) does not specify that the titanium would be commercially pure (CP) titanium.

The ASM Handbook Volume 2 discloses where commercially pure (CP) titanium would be used in applications where high strength is not a requirement and corrosion resistance is important (pg. 588, col. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use commercially pure (CP) titanium, as disclosed by the ASM Handbook Volume 2, as the titanium for the stent that would be fabricated from the titanium and/or tantalum alloy stent, as disclosed by Lau et al. ('158) in view of Lenning et al. ('503), in order to ensure corrosion resistance, as disclosed by the ASM

Handbook Volume 2 (pg. 588, col. 3).

In regards to claims 17 and 18, Lenning et al. ('503) discloses an alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium (col. 2, lines 20-26).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503), and further in view of Scott et al. (US 5,383,928).

Lau et al. ('158) in view of Lenning et al. ('503) discloses a balloon expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium and/or tantalum alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium. However, Lau et al. ('158) in view of Lenning et al. ('503) does not specify that the body would include a therapeutic agent.

Scott et al. ('928) discloses applying a sheath comprising a polymer and a drug for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen in order to allow controlled release of the drug (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a sheath comprising a polymer and a drug, as disclosed by Scott et al. ('928), to the balloon expandable stent, as disclosed by Lau et

al. ('158) in view of Lenning et al. ('503), in order to allow controlled release of the drug, as disclosed by Scott et al. ('928) (abstract).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129) as applied to claim 1 above, with evidence from Wiktor (US 5,653,727).

In regards to claim 21, Fischell et al. ('312) in view of Steinemann et al. ('129) discloses a balloon expandable stent that would comprise a tubular body wherein the stent would be fabricated from titanium or titanium alloy and the titanium alloy would contain 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium. The stent would also include a catheter for delivery into an artery or vessel (col. 1, lines 38-52). However, Fischell et al. ('312) in view of Steinemann et al. ('129) does not specify the diameter of the balloon.

Wiktor ('727) discloses using balloon catheters that have 10 mm and 12 mm diameters to expand a titanium stent (col. 5, lines 58-67 and col. 6, lines 28-52).

Therefore, it would be expected that the size of the expandable balloon of Fischell et al. ('312) in view of Steinemann et al. ('129) would be the same or similar to the size of the balloon of Wiktor ('727) because Fischell et al. ('312) in view of Steinemann et al. ('129) and Wiktor ('727) disclose substantially the same system; expanding a titanium alloy; and the same intended use (use in the human body).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et

al. (US 5,728,158) in view of Lenning et al. (US 3,161,503) as applied to claim 1 above, with evidence from Wiktor (US 5,653,727).

In regards to claim 21, Lau et al. ('158) in view of Lenning et al. ('503) discloses a balloon expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium and/or tantalum alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium. However, Lau et al. ('158) in view of Lenning et al. ('503) does not specify the diameter of the balloon.

Wiktor ('727) discloses using balloon catheters that have 10 mm and 12 mm diameters to expand a titanium stent (col. 5, lines 58-67 and col. 6, lines 28-52).

Therefore, it would be expected that the size of the expandable balloon of Lau et al. ('158) in view of Lenning et al. ('503) would be the same or similar to the size of the balloon of Wiktor ('727) because Lau et al. ('158) in view of Lenning et al. ('503) and Wiktor ('727) disclose substantially the same system including the expanding of a titanium alloy and the same intended use.

NEW GROUND(S) OF REJECTION

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al .(US 4,040,129).

In regards to claim 18, Fischell et al. ('312) discloses a balloon expandable stent that would comprise a tubular body wherein the stent would be fabricated from titanium

or titanium alloy (Figure 6, col. 1, line 66 - col. 2, line 3 and col. 4, lines 5-19).

Fischell et al. (‘312) discloses a balloon expandable stent having a tubular body that would be made from titanium or titanium alloy as shown above. However, Fischell et al. ('312) does not specify the compositions of biocompatible titanium alloys suitable for use as the stent.

Steinemann et al. ('129) discloses a corrosion resistant alloy that would be used as screws fixed in bones (col. 2, lines 27-46 and col. 4, line 51 - col. 5, line 9) comprising from 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium (col. 3, lines 47-58). These alloys combine corrosion resistance, compatibility, and high strength for uses in surgery (col. 4, lines 25-29).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a balloon expandable stent comprising a tubular body, as disclosed by Fischell et al. ('312), from alloys having 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium, as disclosed by Steinemann et al. ('129), in order to combine corrosion resistance, compatibility, and high strength for uses in surgery (balloon expandable stent), as disclosed by Steinemann et al. ('129) (col. 4, lines 25-29).

Still regarding claim 18, Steinemann et al. (‘129) discloses a titanium alloy having 48 weight percent zirconium and 4 weight percent molybdenum (Example 6). The Examiner notes that the range of 3-30 weight percent of one or more elements from the

group of niobium, tantalum, chromium, molybdenum, and aluminum with the balance being titanium and/or zirconium as disclosed by Steinemann et al. ('129) (col. 3, lines 47-58) would read on "25 weight % Zr + 5% Mo" and "49 weight % Zr + 5% Mo" as instantly claimed because Steinemann et al. ('129) discloses alloys with compositions that overlap the compositions of the instant invention.

With respect to the recitation "CP Titanium", which would indicate commercially pure titanium, the Examiner notes that merely changing the purity of a product would not render the product unobvious over the prior art. MPEP 2144.04 (VII).

(10) Response to Argument

First, the Appellant primarily argues that the combination of Lau et al. ('158) in view of Lenning et al. ('503) is improper because a person of ordinary skill in the field of stent design looking to make a better stent would not look at alloys used in autoclaves and the disclosures of Lau et al. ('158) and Lenning et al. ('503) would not give a person of ordinary skill in the field of stent design any reason to make the stent of Lau et al. ('158) out of the alloys disclosed by Lenning et al. ('503) because Lenning et al. ('503) describes alloys suitable for use in highly corrosive and high temperature environments wholly dissimilar from the type of environments experienced by Lau et al. ('158). The Appellant further argues that the alloy of Lenning et al. ('503) would have to have a host of other properties suitable for the stent of Lau et al. ('158) such as being capable of being deformed under normal physiological conditions and one of ordinary skill in the field of stent design would not make the proposed substitution in order to improve

corrosion resistance because Lenning et al. (‘503) does not disclose or even suggest that the alloys would have a greater corrosion resistance than the tantalum disclosed by Lau et al. ('158).

In response, the Examiner notes that Lenning et al. (‘503) discloses and one having ordinary skill in the art of tantalum, titanium, and tantalum-titanium alloys would be well aware that although pure tantalum metal would be corrosion resistant, pure tantalum would also be very expensive (col. 2, lines 7-19) and although Lenning et al. ('503) discloses outstanding corrosion resistant properties while heating to temperatures of up to 800°F (col. 9, lines 44-62), the Examiner concludes that these outstanding corrosion resistant properties would still be present if the alloy were at room temperature. Furthermore, one of ordinary skill in the art would find it desirable to improve upon the generic tantalum alloy as disclosed by Lau et al. ('158), by using beta stabilizers such as vanadium, chromium, molybdenum, iron, and manganese with the balance being titanium, as disclosed by Lenning et al. (‘503) in order to reduce the production cost and improve corrosion resistance over generic tantalum alloys, as disclosed by Lenning et al. ('503) (col. 2, lines 7-19 and col. 9, lines 44-62). Also, an autoclave, as disclosed by Lenning et al. (‘503) (col. 6, lines 48-64) would be a means for sterilizing medical equipment such as stents which would be too expensive to be replaced after each use. Thus, for the purposes of sterilization, one having ordinary skill in the art of stent design would be motivated to know and apply the composition of the alloys used for an autoclave (especially the internal parts), which would include the tantalum-titanium alloys disclosed by Lenning et al. ('503), to medical equipment

because the composition of these internal parts would be subject to constant exposure to temperatures of up to 800°F, as would be the medical equipment during sterilization. In response to the Appellant's argument that the alloy of Lenning et al. ('503) would have to have a host of other properties suitable for the stent of Lau et al. ('158) such as being capable of being deformed under normal physiological conditions, the Examiner notes that Lenning et al. ('503) also discloses that the alloy would have high strength in addition to good ductility up to about 800°F, which would include room temperature (col. 2, lines 20-41).

Second, the Appellant primarily argues that the Examiner's interpretation of Lau et al. ('158) passage at col. 7, lines 5-7 is incorrect and is only a part of the phrase "superelastic NiTi alloys" and does not modify the words "titanium" or "tantalum" and only pure titanium and tantalum are known materials for the production of a stent and if the word "alloys" does modify the other materials in the list that would not result in a disclosure of an alloy of both titanium and tantalum as alleged by the Examiner.

In response, the Examiner notes that stainless steel would be an alloy as would NiTi. Thus, one skilled in the art would read phrase "The tubing may be made of suitable biocompatible materials such as stainless steel, titanium, tantalum, and superelastic NiTi alloys and even high strength thermoplastic polymers.", as including titanium and tantalum alloys. Further, the modification of Lenning et al. ('503) would allow for the production of a tantalum and titanium containing alloy having corrosion resistance that approaches pure tantalum, an improvement over generic tantalum alloy at a lower cost.

Third, the Appellant primarily argues that there is no disclosure in Steinemann et al. (‘129) that suggests that the alloys would be useful for implants that do not contact bone. The Appellant further argues that the proposed combination of Fischell et al. (‘312) with Steinemann et al. (‘129) is improper because a person of ordinary skill in the field of stent design would not find any reason within Fischell et al. (‘312) or Steinemann et al. (‘129) to use the alloys of Steinemann et al. ('129), as opposed to the titanium disclosed by Fischell et al. ('312), to produce the stent of Fischell et al. ('312); because the stent of Fischell et al. (‘312) is not disclosed as being used to bridge bone (and is not connected to or even adjacent bone), a person of ordinary skill in the field of stent design would not find any reason to use any alloy disclosed by Steinemann et al. ('129) to produce the stent of Fischell et al. ('312); and the Examiner's alleged combination "in order to combine corrosion resistance, compatibility, and high strength for uses during surgery” is flawed because it fails to consider that one having ordinary skill would recognize that titanium is already a sufficiently corrosion resistant and sufficiently tissue compatible material and that the "high strength" of the alloys disclosed by Steinemann et al. (‘129) is inapplicable to stents and irrelevant to stent design because stents are not implanted within or against the bone.

In response to Appellant’s argument that the references fail to show certain features of Appellant’s invention, it is noted that the features upon which Appellant relies (i.e., lack of contact with bone) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.

Cir. 1993). In response to the Appellant's argument that a person of ordinary skill in the field of stent design would not find any reason within Fischell et al. ('312) or Steinemann et al. ('129) to use the alloys of Steinemann et al. ('129), as opposed to the titanium disclosed by Fischell et al. ('312) to produce the stent of Fischell et al. ('312), the Examiner notes that Fischell et al. ('312) discloses using titanium or titanium alloys (col. 4, lines 5-19) and thus the Appellant's argument is unpersuasive because Fischell et al. ('312) would not be limited to only titanium materials. In response to the Appellant's argument that the stent of Fischell et al. ('312) is not disclosed as being used to bridge bone (and is not connected to or even adjacent bone) and a person of ordinary skill in the field of stent design would not find any reason to use any alloy disclosed by Steinemann et al. ('129) is unpersuasive because one having ordinary skill upon reading Fischell et al. ('312) would seek known titanium alloys having biocompatibility for stent design and thus would find the known medical titanium alloys of Steinemann et al. ('129) applicable because of their biocompatibility. In response to the Appellant's argument that the Examiner's alleged combination "in order to combine corrosion resistance, compatibility, and high strength for uses during surgery" is flawed because it fails to consider that one having ordinary skill would recognize that titanium is already a sufficiently corrosion resistant and sufficiently tissue compatible material and that the "high strength" of the alloys disclosed by Steinemann et al. ('129) is inapplicable to stents and irrelevant to stent design because stents are not implanted within or against the bone, the Examiner asserts that the Appellant is only considering using titanium metal for the stent and not titanium alloys. All titanium alloys would not necessarily be

sufficiently corrosion resistant and tissue compatible. In considering the combinability of Fischell et al. ('312) and Steinemann et al. ('129), the Appellant is discounting that both references disclose biocompatible metal alloys and the relevance of whether or not the stent would be implanted within or against the bone would be irrelevant because the claims do not limit the structure such that the stent would not be capable of being implanted within or against the bone. Furthermore, the strength of the alloys used for stents would be considered because one skilled in the art would desire long-term use and a minimization of breakage during use.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR

41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Jessee Roe/

Examiner, Art Unit 1793

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Gregory L Mills/

Supervisory Patent Examiner, Art Unit 1700

Conferees:

/Roy King/

Supervisory Patent Examiner, Art Unit 1793

/Gregory L Mills/

Supervisory Patent Examiner, Art Unit 1700